

needle extending from one end and a flexible tubing connected to the other end for establishing a fluid communication path between the tubing and the needle. A housing is integrally molded to and extending from the one end of the body.

Thus, in all of the embodiments set forth in the pending independent claims, the device of the instant invention is a single molded device that does not have any separate components. In other words, the device is produced from a single mold, be it the intravenous device as set forth in claims 39 and 44, or the winged device as set forth in claim 48. By thus forming the complete device from a single mold, the manufacturing of the device of the instant invention is greatly expedited, and the cost of the manufacturing process is greatly reduced.

Contrast the instant device with the prior art devices as disclosed by the above-noted reference. In particular, Sweeney discloses a syringe that has connected thereto a separable needle assembly which in turn is separable into a needle hub 22 and a housing 36. As clearly shown, housing 36 is connected to needle hub 22 by means of cooperating hinges 50 that are made up of extending fingers and cooperating holes. Sweeney does not disclose any body that has a through passage to which one end has a needle and another end has a flexible tube.

Newby was cited by the examiner to show the flexible tube. Yet Newby, like Sweeney, also discloses a needle assembly that is made up of a number of separable components. To wit, Fig. 2 shows a double ended needle 40 to which one end is fitted a collar 90 that has a hook member 114 to which is snap-fitted, by means of a hanger bar 182, the needle protection housing 140. The snap-fitting of a needle housing to a collar by means of a cooperating hanger bar and hook member is disclosed throughout Newby. Indeed, in Fig. 17 which shows an intravenous device, Newby states: "For purposes of illustration, shield 140a and collar 90a are connected to a conventional IV infusion set ..." (column 7, lines 14-15). Newby likewise fails to disclose a body that has a through passage.

The examiner has relied upon Burns for suggesting that a housing may be molded to the main body of the device. But in actuality, Burns discloses something totally different. With reference to Fig. 1, the needle assembly disclosed in Burns in fact comprises a double ended needle and a shield 38 that is connected to a mounting 48, which is used for holding shield 38 onto hub 20 of the double-ended needle (column 4, lines 19-27). As disclosed, it is imperative for the Burns device that mounting 48 be separate component insofar as it allows shield 38 to be freely rotated about hub 20. Fig. 4 of Burns relied by the examiner in fact shows the shield and its hub, and nothing more.

In contrast, as was noted earlier, the instant invention discloses a unitary molded device that includes both a main body having attached thereto a needle and a flexible tube and a housing integrally connected thereto. Nothing in any of the references relied upon by the examiner suggests such unitary device. If anything, each of the relied upon references discloses separate components that need to be assembled together to form the device as disclosed. The so-called one-piece molded unit shown in Fig. 4 of Burns that allegedly shows molding in fact is but a single component of the needle assembly of Burns, which device is disclosed as having to be assembled from different components.

In sum, there is nothing in any of the cited references that discloses or suggests a single unitary device as set forth in the pending claims. That being the case, there could not be any motivation for making the combination as asserted in the Office Action, insofar as the combination of all three references nonetheless falls far short of the claimed invention.

Claims 39-41, 44-46 and 48-52 were also rejected under the combination of Newby in view of Burns. For this rejection, the examiner asserts that "Furthermore, Fig. 17 (of Newby) best shows intravenous device body construction where the body is integrally (meaning used: "formed as a unit with another part) attached to the tubing, needle and housing. The definition of the term Integral appears below in Response to Arguments. Finally, the device is considered one-piece once assembled and during use."

As noted above, Newby clearly discloses that the shield 140a and collar 90a are connected to a conventional IV infusion set 200. There is therefore nothing "integral" with respect to Fig. 17 of Newby. The examiner is correct with respect to the definition of the word "integral" as "formed as a unit with another part". The operative phrase here is as a unit. And such a unit can readily be referred to in Fig. 8 of the specification which shows a single integral unit. There is no such integral unit disclosed in Fig. 17 of Newby. As was pointed out earlier, Newby in fact teaches otherwise. The same argument above in regard to Burns is equally applicable herein insofar as Fig. 4 of Burns shows but a single component of the needle assembly device disclosed therein.

In view of the foregoing, applicant respectfully submits that the claimed invention is patentably distinguishable over the prior art. Accordingly, the examiner is respectfully requested to reconsider the application and allow the pending claims at an early date.

Respectfully submitted,



Louis Woo, Reg. No. 31,730
Law Offices of Louis Woo
717 North Fayette Street
Alexandria, VA 22314
Phone: (703) 299-4090

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